

## REMARKS

Claims 1-6 are pending in the instant application. The sole basis for the Examiner's rejection of claims 1-6 are addressed below.

### **35 USC 112, first paragraph – Enablement**

The Examiner rejected claims 1-6, drawn to a method for preventing, treating or ameliorating inflammation using (–)-hydroxycitric acid (HCA), pursuant to 35 U.S.C. § 112, first paragraph as non-enabled due to over breadth. Specifically, the Examiner alleges that, while the specification enables treating or ameliorating inflammation, it does not reasonably provide enablement for preventing inflammation using HCA. That is, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with the above-referenced claims.

Applicant traverses.

The Examiner's rejection of claims 1-6 pursuant to 35 U.S.C. §112, first paragraph is based in part, on the Examiner's erroneous belief that "[t]here are no examples directed to preventing inflammation" in the application and, therefore, that "one of ordinary skill in the art would be burdened with undue experimentation to determine if the claimed compound is capable of preventing inflammation." Office Action at page 6, subpoint #7 through subpoint #8. Applicant disagrees.

Example 1 of the specification, as originally filed, presents data which demonstrates that administration of HCA to a subject prevents inflammation. Example 1 describes studies examining the effect of various forms of HCA on diet-induced elevation of c-reactive protein (CRP), a known biological marker of inflammatory diseases (Hilliquin P., Biological markers in inflammatory rheumatic diseases. *Cell Mol Biol* (Noisy-le-grand), 1995 Dec;41(8):993-1006). See, Instant Application, Pub. No. US 2005/0032901, at ¶¶ 22-26. Specifically, rats were fed a diet composition known to promote a variety of metabolic imbalances and dysfunctions. See, Instant Application, Pub. No. US 2005/0032901, at ¶ 22. Indeed, as shown in Example 1, control rats fed this diet showed an elevation, *i.e.*, ΔOD 339, in serum CRP over the 4-week study period. However, the administration of select HCA compositions prevented the diet-mediated elevation of serum CRP observed in control animals, see, *e.g.*, KMgHCA(r) (ΔOD - 145); KMgHCA (h) (ΔOD -113); and KHCA (ΔOD-155). See, Instant Application, Pub. No. US 2005/0032901, at ¶¶ 23. Thus, the application, as originally filed, enables any person skilled in

Appl. No. 10/612,648  
Express Mail No. EV 669114091US  
Resp. to Office Action of November 16, 2005  
Response dated February 15, 2006

Attorney Docket No. 350957-0105 (Formerly 71286-010510)

the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with the above-referenced claims as the art teaches that CRP is a biological marker of inflammatory diseases and the specification demonstrates prevention of diet-mediate elevation of serum CRP in rats. Accordingly, the Applicant respectfully requests reconsideration and withdrawal of the 35 U.S.C. § 112, first paragraph rejections for lack of enablement.

### CONCLUSION

Applicant respectfully submits that the pending claims are in condition for allowance and respectfully request the same. If there are any questions regarding these remarks, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

Respectfully submitted,



Michel Morency, Reg. No. 50,183  
James F. Ewing, Reg. No. 52,875  
Attorneys for Applicant  
Foley & Lardner LLP  
111 Huntington Avenue, 26<sup>th</sup> Fl.  
Boston, MA 02199  
Tel. 617-342-4000  
Fax. 617-342-4001

February 15, 2006